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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/696,381	10/28/2003	Albert K. Chin	80121-08565	8269
758 7590 12/26/2007 FENWICK & WEST LLP SILICON VALLEY CENTER 801 CALIFORNIA STREET MOUNTAIN VIEW, CA 94041			EXAMINER SMITH, PHILIP ROBERT	
			ART UNIT 3739	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/696,381	Applicant(s) CHIN, ALBERT K.	
	Examiner Philip R. Smith	Art Unit 3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 September 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) 11 and 12 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>7/24/07</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

- [01] The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
- [02] The rejection of claims 1-2,4-10 as being anticipated by Gibson (702,789) set forth in the Office action of 7/17/2007 are withdrawn in view of the amendments of 9/27/2007.
- [03] Claims 1-2,6,10 are rejected under 35 U.S.C. 102(b) as being anticipated by Horzewski (5,318,588).
- [04] With regard to claim 1: Horzewski discloses an apparatus for performing a surgical procedure comprising:
- [04a] an inner cannula ("dilator 150" 12/49) having an elongated body and a tip ("bulbous region 127" 12/64) that is positioned at a distal end of the elongated body and that is configured to dissect tissue ("dilator 150 contains a guidewire channel 122" 12/49); and
- [04b] an outer expandable sheath ("side arm sheath 90" 11/67) disposed about the inner cannula and configured to expand in an outward direction ("accommodate positive radial expansion over a specific range of radial dimensions" 12/7-9) responsive to the tip of the inner cannula slidably passing longitudinally through the sheath ("Withdrawal of the dilator [150], however, through the confines of the sheath, increases the profile of the delivery channel to the desired profile as bulbous region 127 is withdrawn through the shaft" 13/12-15).
- [05] With regard to claim 2: As noted above, Horzewski discloses that the tip ("127") has an outer dimension greater than an inner dimension of the sheath ("maximal profile of the bulbous region 127

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of dilator 150 corresponds to the intended channel profile of the device" 13/14) and includes: a proximal tapered end for facilitating passing of the tip through the sheath (see Fig 6B).

[06] With regard to claim 6: the inner cannula and outer expandable sheath disclosed by Horzewski are separable to allow the outer expandable sheath to remain in place at a surgical site as the inner cannula and the tip attached thereto are withdrawn ("installing dilators of progressively larger cross-sectional profiles" 13/20-22).

[07] With regard to claim 10: as shown in Fig 6B, Horzewski discloses that the tip ("127") further comprises a distal tapered end ("leading taper 123") for dissecting tissue, a proximal tapered end ("expansion taper 124"), and an enlarged intermediate portion having an outer dimension greater than an inner dimension of the sheath for exerting lateral expansion force against the outer expandable sheath responsive to slidable passage of the tip longitudinally through the outer expandable sheath ("maximal profile of the bulbous region 127 of dilator 150 corresponds to the intended channel profile of the device" 13/14, as noted above).

Claim Rejections - 35 USC § 103

[08] The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

[09] Claims 4-5,7-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Horzewski (5,318,588) in view of Davis (6,030,406).

[10] Horzewski discloses a cannula having a tip, as noted above.

[11] Horzewski does not disclose that the tip is transparent and the apparatus further comprises an endoscope disposed within the cannula for providing endoscopic visualization of the surgical procedure through the transparent tip.

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- [12] Davis discloses a cannula having a "transparent tip 13" (4/64-5/18) which "facilitates visualization of the tissue being dissected" (14/57), in addition to an endoscope, for visualization (5/1).
- [13] At the time of the invention, it would have been obvious to a person of ordinary skill in the art that the cannula disclosed by Horzewski have a transparent tip as taught by Davis. A skilled artisan would be motivated to provide a transparent tip in order to facilitate visualization of the subject being dissected, as taught by Davis.

Claim Rejections - 35 USC § 103

- [14] Claims 4-5,7-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Horzewski (5,318,588) in view of Gibson (702,789).
- [15] With regard to claim 4:
- [15a] As noted above, Horzewski discloses an outer expandable sheath configured to expand in an outward direction responsive to the tip of the inner cannula slidably passing longitudinally through the sheath. The outer expandable sheath disclosed by Horzewski is not composed of first and second shells.
- [15b] Gibson discloses an outer expandable sheath ("tube A" 1/28) configured to expand in an outward direction responsive to the tip of an element ("rod D" having "plunger D2" 2/65) slidably passing longitudinally through the sheath (2/71-89). Gibson further discloses that the outer expandable sheath comprises a first shell and a second shell ("segmental bars e'," 2/60-70) adjacently aligned along longitudinal edges thereof, and a resilient connector ("thin soft rubber sheath C," 2/81) attached between the first and second shells for resiliently urging the longitudinal edges of the Shells together.

- [15c] At the time of the invention, it would have been obvious to a person of ordinary skill in the art that the outer expandable sheath having resiliently connected first and second shells disclosed by Gibson be substituted for the outer expandable sheath disclosed by Horzewski. It is obvious to substitute one known element for another to obtain predictable results. Radially expansive tubes are known in the art, as are radially expansive shells. A skilled artisan could have substituted one for the other, and the resulting substitution would have been predictable.
- [16] With regard to claim 5: Gibson further discloses that the outer expandable sheath further comprises a retainer ("nut E," 2/74) disposed near the proximal end of the shells for retaining the shells against relative longitudinal movement during passage of the inner cannula through the outer expandable sheath.
- [17] With regard to claim 7: the resilient connector disclosed by Gibson resiliently urges a distal end of the first shell toward a distal end of the second shell (a point indicated by "a2" in the figures) to form an inner dimension at the distal end of the outer expandable sheath smaller than the outer dimension of the tip in the absence of an outwardly expansive force applied to the distal end of the outer expandable sheath in response to the tip passing through the distal ends of the shells.
- [18] With regard to claim 8: Gibson further discloses that the outer expandable sheath further comprises: a second resilient connector ("nut E," 2/74) disposed to resiliently urge a proximal end of the first shell toward a proximal end of the second shell to form an inner dimension at the proximal end of the outer expandable sheath smaller than the outer dimension of the tip in the absence of an outwardly expansive force applied to the proximal end of the outer expandable sheath in response to the tip passing through the proximal ends of the shells.

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- [19] With regard to claim 9: Gibson discloses that at least one of the shells of the outer expandable sheath is flexible to bend in response to passing of the tip through the outer expandable sheath (2/75, with reference to Figure 2).

Response to Arguments

- [20] Applicant's arguments have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

- [21] The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Guignard (5,411,517) discloses an expandable outer sheath responsive to advancement of an inner cannula. Mackenzie (6,019,777) discloses an outer expandable sheath responsive to inflation of an inner cannula.
- [22] Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).
- [23] A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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- [24] Any inquiry concerning this communication or earlier communications from the examiner should be directed to Philip R. Smith whose telephone number is (571) 272 6087 and whose email address is philip.smith@uspto.gov. The examiner can normally be reached between 9:00am and 5:00pm.
- [25] If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (571) 272 4764.
- [26] Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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